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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Confirmation No. 7242  
Minoru FUJIMORI et al. : Docket No. 2001-0206A  
Serial No. 09/816,391 : Group Art Unit 1635  
Filed March 26, 2001 : Examiner B. Whiteman  
ANAEROBIC BACTERIUM AS A DRUG :  
FOR CANCER GENE THERAPY :

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES  
OR IN A NAFTA OR WTO MEMBER COUNTRY  
TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. 1.131)**

Assistant Commissioner for Patents,  
Washington, D.C. 20231

Sir:

1. This declaration is to establish completion of the invention in this application in the United States, at a date prior to March 27, 2000 and August 7, 2000, that are the effective dates of the prior art:

☒ Publications

- A. *Yazawa et al., Bifodobacterium longum as a delivery system for cancer gene therapy: Selective localization and growth in hypoxic tumors, Cancer Gene Therapy, Vol. 7, No 2, pp. 269-274, March 27, 2000*
- B. *Babincova et al., Anaerobic bacteria as a luciferase gene delivery system for endogenous generation of photodynamic light inside tumors, Life and Medical Sciences Online, <http://www.itrust.de/lamso/lpext.dll.Infobase0?title0003.htm?fn=docu>, pp. 1-4, August 7, 2000*

☐ Patent

that was cited by the

☒ Examiner and

☒ Applicants

2. The person making this declaration is (are):

- ☒ the inventor(s).
- ☐ only some of the joint inventor(s) (and a suitable excuse is attached for failure of the omitted joint inventor(s) to sign)
- ☐ the party in interest (and a suitable explanation as why it is not possible to produce the declaration of the inventor(s) is attached)

### FACTS AND DOCUMENTARY EVIDENCE

3. To establish the date of completion of the invention of this application, the following attached document and certification are submitted as evidence:

- A. Yazawa et al., Bifodobacterium longum as a delivery system for cancer gene therapy: Selective localization and growth in hypoxic tumors, Cancer Gene Therapy, Vol. 7, No 2, pp. 269-274, published March 27, 2000, submitted January 14, 1999, and accepted May 31, 1999.
- B. Supporting statement by Jennifer English, Assistant Editor, Nature Publishing Group, certifying that the above document was published on March 27, 2000.

From this document and statement, it can be seen that the invention in this application was made

☐ on \_\_\_\_\_.

☒ at least by the date of January 14, 1999, which is a date earlier than the effective date of the references.

It is recognized that the document being used to establish the date of the invention is the same as one of the prior art reference (Yazawa et al.) upon which a 35 U.S.C. § 102(a) rejection is based. However, it should be noted that the listed authors of the present document comprise five out of the seven inventors for the present application. Thus, the experiments and laboratory

work performed by these inventors as disclosed in the supporting document clearly establish conception, due diligence and reduction to practice prior to the publication dates of March 27, 2000 and August 7, 2000 since the document was submitted for publication on January 14, 1999 and accepted on May 31, 1999.

#### **TIME OF PRESENTATION OF THE DECLARATION**

(complete (a), (b) or (c))

- (a)    ☒    This declaration is submitted prior to final rejection.
- (b)    ☐    This declaration is submitted with the first response after final rejection, and is for the purpose of overcoming a new ground of rejection or requirement made in the final rejection.
- (c)    ☐    This declaration is submitted after final rejection. A showing under 37 CFR 1.116(b) is submitted herewith.

#### **DECLARATION**

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code , and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**SIGNATURE(S)**

7. (complete A or B below)

A. Inventor(s)

Full name of sole or first inventor \_\_\_\_\_

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_

\_\_\_\_\_

Full name of second joint inventor, if any \_\_\_\_\_

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_

**B. Assignee**

\_\_\_\_\_  
(type or print name of person signing)

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
Date

\_\_\_\_\_  
P.O. Address

\_\_\_\_\_  
(type name of assignee)

\_\_\_\_\_  
Address of assignee

\_\_\_\_\_  
Title of person authorized to sign  
on behalf of assignee

Assignment recorded in PTO on \_\_\_\_\_  
Reel \_\_\_\_\_ Frame \_\_\_\_\_

A "CERTIFICATE UNDER 37 CFR 3.73(b)" is attached.

Attorney's Docket No. \_\_\_\_\_

**ADDED PAGE FOR SIGNATURE BY THIRD AND  
SUBSEQUENT INVENTORS**

**(DECLARATION OF PRIOR INVENTION IN THE UNITED STATES  
OR IN A NAFTA OR WTO MEMBER COUNTRY  
TO OVERCOME CITED PATENT OR PUBLICATION (37 CFR 1.131) )**

Full name of **third** joint inventor, if any \_\_\_\_\_

**Inventor's signature** \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_

Full name of **fourth** joint inventor, if any \_\_\_\_\_

**Inventor's signature** \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_

Full name of **fifth** joint inventor, if any \_\_\_\_\_

**Inventor's signature** \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_  
\_\_\_\_\_

Full name of **sixth** joint inventor, if any \_\_\_\_\_

**Inventor's signature** \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_  
\_\_\_\_\_

Full name of **seventh** joint inventor, if any \_\_\_\_\_

**Inventor's signature** \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_  
\_\_\_\_\_